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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/702,037 | 10/27/2000 | Peter Bennett Duff Whyte | U013032-6 | 8344 |

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William R. Evans
c/o Ladas & Parry
26 West 61st Street
New York, NY 25858

| EXAMINER | |
|---|---|
| WARE, DEBORAH K | |
| ART UNIT | PAPER NUMBER |
| 1651 | |

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/702,037 | Whyte |
| **Examiner** | **Art Unit** |
| Deborah Ware | 1651 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Feb 20, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1, 3, 4, and 11-27* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3, 4, and 11-27* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1, 3-4 and 11-27 are presented for examination on the merits.

Cancellation of non-elected claims is acknowledged. Further, extension for 3 months time and amendment filed February 20, 2003, have been received and entered of record.

1. The following guidelines are reiterated again to illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.

(b) Cross-Reference to Related Applications.

(c) Statement Regarding Federally Sponsored Research or Development.

(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).

(e) Background of the Invention.

1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.

(g) Brief Description of the Several Views of the Drawing(s).

(h) Detailed Description of the Invention.

(I) Claim or Claims (commencing on a separate sheet).

(j) Abstract of the Disclosure (commencing on a separate sheet).

(k) Drawings.

(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

Further, it is suggested that in the specification IGF-1 and other abbreviations should be initially defined to ensure that their meaning as recognized in the art is intended. This is merely a suggestion and Applicant's cooperation is appreciated.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The prior office action is reiterated below and answers to Applicant's arguments follow each reiterated art rejection as follows:

2. Claims 1 and 3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Aalto et al. (A).

doesn't teach retentate

The claims are drawn to a composition comprising colostrum or a fraction thereof, wherein the fraction includes IGF-I and the composition may include casein of which is colostrum derived and maintained therein following fractionation of the colostrum.

Aalto et al. teach a composition comprising colostrum or a fraction thereof, wherein the fraction includes IGF-I and the composition may include casein of which is colostrum derived and maintained therein following fractionation of the colostrum. Note column 1, lines 10-15 and 50-55 and column 2, lines 1-6 and column 5, lines 4, 7-8 and 17-20. Bovine colostrum contains casein and fractions of bovine colostrum containing casein may be desirable as disclosed by the cited reference. Also bovine colostrum may be frozen at the farm and further contains growth factors such as IGF.

The claims are identical to the teaching of Aalto et al. and are therefore, considered to be anticipated by the teachings of this cited reference. Each of the claimed features of the composition are disclosed. The claims are identical to the disclosure of Aalto et al. Applicant's argument that the present invention utilizes a retentate is noted, however, the claims are not so limited to any retenate. Each of the claim limitations of a composition comprising colostrum and further including IGF-1 growth factor are disclosed by Aalto et al. Note col. 3, lines 9-10, for example. The claims do not require the presence of casein. However, the reference merely teaches the optional removal of casein and at col. 10, all lines, casein is inherently in the colostrum fraction of the patented claim 1 since in dependent claim 2 casein is optionally removed. The claimed and disclosed compositions appear to be identical and the claimed one remains anticipated by the teachings of the cited reference.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aalto et al. cited above, in view of newly cited Tokoro (A), see enclosed PTO-892 Form.

Aalto et al. clearly teach ultrafiltration, note the abstract and further, teach if desired the fraction can be lyophilized. Note col. 5, lines 35-37. Also ultrafiltration is disclosed. See the abstract.

Tokoro teaches at col. 6, lines 23-25, that lyophilizing or spray drying is conventional in the art for drying products.

The claims differ from Aalto et al. in that ultrafiltration technique is not disclosed to include spray drying.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was filed to replace lyophilizing disclosed by Aalto et al. with the spray drying step disclosed by Tokoro in order to provide for the ultrafiltration preparation process as claimed herein. The claims are prima facie obvious since one of skill would have expected successful results with use of either conventional technique and to select for spray drying in place of lyophilizing is within the purview of an ordinary artisan.

5. Claims 17-18 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by AU-A-39340/89, Borody et al., for reasons of record.

Claims drawn to a method of treating or preventing a disorder of the gut wherein the disorder is caused by several different things, one of which is infections resulting from HIV. Treatment includes administering composition comprising colostrum. Also drawn to improving gut growth and performance. Also treating small bowel syndrome.

The reference teaches a method of treating or preventing a disorder of the gut wherein the disorder is caused by several different things, one of which is infections resulting from HIV. Note page 1-2, all lines. Also note pages 3-4, all lines. Colostrum is administered. Further, small bowel syndrome is treated with the colostrum, see page 1, lines 15-20. Further, gut growth and performance are disclosed.

The claims are identical to the cited reference and are, therefore, considered to be anticipated by the teachings of the cited reference. The argument that the claims avoid use of pasteurization is noted but the claims are not so limited. The claims also do not require ultrafiltration, nor does the art require the removal of casein, note above. The claims remain to be anticipated by the teachings of Borody et al.

6. Claims 14, 16, 19 and 23-25 and rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/10192, for reasons of record.

Claims are drawn to a method of increasing recovery after exercise, improving peak power or peak force, and increasing endurance exercise performance by administering food composition of claim 1. Also drawn to method of reducing fatigue, muscle damage and increasing vertical jump using composition of claim 1

The reference teaches the same, note page 1, lines 1-5 , see page 2, all lines and the abstract.

The claims are identical to the cited reference and are therefore considered to be anticipated by the teachings of the cited reference. Applicants' argument that the alleged removal of casein as disclosed by the cited reference is paramount to the difference between their claimed invention and the disclosed is noted. However, the claims do not necessarily require the presence of casein. All that is required is the presence of colostrum in a food. Thus, the arguments are not deemed persuasive and the rejection is maintained.

7. Claims 11-13, 15, 20, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark, 1996, for reasons of record.

Claims drawn to methods of changing body composition, increasing tissue mass, increasing fat utilization, increasing height, increasing physiological buffering capacity, reducing fat mass and improving bioavailability of components in colostrum by administering the composition of claim 1, colostrum.

Clark teaches colostrum stimulates bone and muscle growth and nerve regeneration, increase body weight of lean muscle, protects against the bacteria that cause stomach ulcers, etc., note first few pages, both columns and all lines.

The claims are identical to the cited disclosure and are considered to be anticipated by the teachings of the cited reference. Increasing tissue mass and change of body composition are inherent to the teachings that muscle growth occurs with colostrum because tissue mass would

inherently increase as would fat utilization, and changing body composition and reduction in fat mass and an overall improvement of bioavailability. Further, buffering capacity would inherently increase since the reference teaches that colostrum protects against the bacteria that cause ulcers. Ulcers reduce buffering capacity. Further, height would inherently increase since colostrum is taught to stimulate bone and muscle growth. The argument which is set forth again in regard to the presence of casein not a part of the cited disclosure is noted. However, once again Applicant needs to note that the claims do not necessarily require the presence of casein and all that is required is colostrum in the composition. Instantly filed claim 1 does not necessarily require casein. Therefore, Applicant's arguments are not deemed persuasive since they are directed toward subject matter which is not claimed as directed to claims 11-13, 15, 20 and 26-27. As discussed above, none of these claims under rejection require ultrafiltration, spray drying, etc. The claims remain considered to be anticipated by the teachings of Clark for these reasons and for those of record.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Deborah K. Ware

May 17, 2003

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651